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| EXAMINER | |
|---|---|
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/777,043 | RAPAPORT, ELIEZER | |
| | Examiner | Art Unit | |
| | JAMES D. ANDERSON | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,2 and 4-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 7-12* is/are rejected.

7)☒ Claim(s) *4-6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claims 1-2 and 4-12 are presented for examination*

Applicants' amendment filed 11/29/2007 has been received and entered into the application. Accordingly, claims 1-2 and 4-6 have been amended and claim 13 has been cancelled.

Applicants' arguments have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### *Response to Arguments*

Applicant's arguments filed 11/29/2007 have been fully considered but they are not persuasive. Applicant submits the following arguments with respect to the 35 U.S.C. 102(b) rejections of claims 1-2 and 7-13 (now 1-2 and 7-12).

Firstly, Applicant argues that claims 1-2 have been amended to recite "an effective amount" of: (a) adenosine and inorganic phosphate; (b) AMP; or (c) ATP and thus the cited references do not anticipate the instant claims because they do not teach administration of an adenosine compound along with caffeine as part of a weight loss program, let alone administration of an effective amount of an adenosine compound. However, the Examiner notes that the instant specification does not define what is meant by an "effective amount" and the preamble of the claim is not linked to the body of the claim in such a way as to convey that the "effective amount" being administered is effective to treat the condition recited in the preamble.

The phrase "an effective amount" has been held to be indefinite when the claim fails to state the function which is to be achieved and more than one effect can be implied from the specification or the relevant art. *In re Fredericksen* 213 F.2d 547, 102 USPQ 35 (CCPA 1954). In this case, the adenosine compounds recited in the instant claims have effects on the human body other than inducing weight loss as recited in the instant claims. As such, recitation of an "effective amount" does not limit the amount of adenosine compound to an amount that elicits weight loss. Further, as noted in the previous Office Action (and acknowledged by Applicant in the present response), food contains adenosine compounds and the cited prior art clearly teaches that the weight loss compositions disclosed therein can be administered with a "normal diet".

Secondly, Applicant argues that the cited prior art teaches administration of caffeine with other active agents (e.g., ephedrine or aspirin and chromium). However, the Examiner notes that the "comprising" language of the instant claims does not preclude the administration of other active agents from the administration of caffeine or theophylline and the claimed adenosine compounds. As such, the fact that the cited references require other active components is not pertinent to the present rejections.

Thirdly, while Applicant concedes that food contains "more than one molecule of ATP, AMP, and adenosine and inorganic phosphate in a form bound to fiber, membrane, protein or other cellular material, Applicant argues that food also contains metabolites, fragmented proteins, fragmented RNA pieces, etc. Applicant further asserts that the instant claims recite a "maximum of two, well-defined active agents" rather than totally undefined mixtures of constituents of food. However, as noted supra, "comprising" language of the instant claims does not preclude the administration of other active agents from the administration of caffeine or

theophylline and the claimed adenosine compounds. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, *e.g.*, *Mars Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term comprising,' the terms containing' and mixture' are open-ended."). *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition comprising' in a method claim indicates that the claim is open-ended and allows for additional steps."); *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). Accordingly, the instant claims do not preclude the consumption of food as a source of the claimed adenosine compounds.

Fourthly, Applicant argues that because food contains not only small amounts of adenosine and inorganic phosphate and AMP and ATP, but also the precursors of bodily energy, namely fats, sugars, and proteins, that food is metabolized mostly to fats with minute amounts of fuel converted to energy in obese or overweight patients. As such, Applicant argues that food consumption will not contribute to liver ATP pools but to the accumulation of fats. However, the Examiner notes that the instant claims do not recite any limitations whereby the amounts of adenosine compounds are required to contribute to liver ATP pools. As such, because the

references cited in the present rejections teach that administration of caffeine-containing compositions in conjunction with a normal diet or breakfast can be used to reduce body weight, and in view of the fact that food contains the claimed adenosine compounds, the rejections are maintained for the reasons of record and reiterated below.

### *Claim Rejections - 35 USC § 112 (2nd Paragraph)*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 and 7-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 2 recite the administration of "an effective amount" of (a) adenosine and inorganic phosphate; (b) AMP; or (c) ATP. This limitation is indefinite because it is not clear what the amount being administered is effective for. The preamble of the claim is not linked to the body of the claim in such a way as to clearly convey that the "effective amount" being administered is effective to treat the condition recited in the preamble. The phrase "an effective amount" has been held to be indefinite when the claim fails to state the function which is to be achieved and more than one effect can be implied from the specification or the relevant art. *In re Fredericksen* 213 F.2d 547, 102 USPQ 35 (CCPA 1954). In this case, the adenosine compounds recited in the instant claims have effects on the human body other than inducing weight loss as recited in the instant claims. As such, recitation of an "effective amount" does not limit the amount of adenosine compound to an amount that elicits weight loss as instantly claimed.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 7, 9-10 and 12 are rejected under 35 U.S.C. § 102(b) as being anticipated by Friedlander (U.S. Patent No. 5,055,460; Issued Oct. 8, 1991) as evidenced by Lehninger (Biochemistry, Worth Publishers, Inc., New York, 1970, pages 289-290).

The instant claims recite administration of caffeine and adenosine and inorganic phosphate, AMP, or ATP in order to induce weight loss of maintain weight reduction in human patients.

Friedlander teaches compositions comprising caffeine, aspirin, and ephedrine, which may be administered concurrently with caloric restriction or with a commercial diet program, for the purpose of reducing weight or maintaining body weight (Abstract; col. 4, lines 15-22). The amount of caffeine is taught to be in the range of 10-500 mg/day, thus reasonably anticipating the instantly claimed 0.1-100 mg/kg/day and 0.1-10 mg/kg/day (col. 4, lines 29-31). The compositions are administered orally or parenterally, thus anticipating the claimed "oral" and "injection" administration routes (col. 5, lines 22-26).

With respect to the claimed "administration" of adenosine and inorganic phosphate, AMP, or ATP, Lehninger is provided as supporting evidence that the consumption of a normal diet will naturally result in the "administration" of ATP and/or AMP as instantly claimed. For example, Lehninger teaches that ATP, ADP, and AMP "...are not trace substances; the sum of

their concentrations in the aqueous phase of various types of intact cells is between 2 and 15 mM" (page 289). These nucleotides are present not only in the soluble cytoplasm but also within organelles such as mitochondria and nuclei (id.). Accordingly, it is the Examiner's position that the consumption of a normal diet or a commercial diet plan will naturally result in the consumption of AMP or ATP because these substances are present in all cells, including the cells of beef products, fish products, chicken products, vegetables, etc.

Claims 1-2 and 7-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Astrup (U.S. Patent No. 5,422,352; Issued Jun. 6, 1995) as evidenced by Lehninger (Biochemistry, Worth Publishers, Inc., New York, 1970, pages 289-290).

The instant claims recite administration of caffeine and adenosine and inorganic phosphate, AMP, or ATP in order to induce weight loss of maintain weight reduction in human patients.

Astrup teaches compositions comprising caffeine and ephedrine for the purpose of reducing weight of a human (Abstract). Theophylline is also taught to be a reasonable substitute for caffeine, as both are thermogenically active xanthines (col. 6, line 65 to col. 7, line 6). The amount of caffeine or other xanthine is taught to be in the range of 80 mg to 1.9 grams per unit dose, preferably 80 mg to 720 mg, and can be administered 1 to 10 times daily, thus reasonably anticipating the instantly claimed 0.1-100 mg/kg/day and 0.1-10 mg/kg/day (col. 8, lines 52-59). The compositions are administered "by any suitable route" such as orally, topically, or parenterally, thus anticipating the claimed "oral", "injection", and topical administration routes (col. 8, lines 60-66). In one study, participants were administered caffeine tablets, ephedrine

tablets, or caffeine/ephedrine tablets and were allowed to eat freely after a light breakfast and standardized lunch (col. 23, lines 29-52).

With respect to the claimed "administration" of adenosine and inorganic phosphate, AMP, or ATP, Lehninger is provided as supporting evidence that the consumption of a normal diet will naturally result in the "administration" of ATP and/or AMP as instantly claimed. For example, Lehninger teaches that ATP, ADP, and AMP "...are not trace substances; the sum of their concentrations in the aqueous phase of various types of intact cells is between 2 and 15 mM" (page 289). These nucleotides are present not only in the soluble cytoplasm but also within organelles such as mitochondria and nuclei (id.). Accordingly, it is the Examiner's position that the consumption of a normal diet or a commercial diet plan will naturally result in the consumption of AMP or ATP because these substances are present in all cells, including the cells of beef products, fish products, chicken products, vegetables, etc.

Claims 1-2, 7, 10, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Allen (U.S. Patent No. 5,480,657; Issued Jan. 2, 1996) as evidenced by Lehninger (Biochemistry, Worth Publishers, Inc., New York, 1970, pages 289-290).

The instant claims recite administration of caffeine and adenosine and inorganic phosphate, AMP, or ATP in order to induce weight loss of maintain weight reduction in human patients.

Friedlander teaches compositions comprising caffeine, fructose, and chromium for the purpose of reducing weight or maintaining body weight, which may be consumed with meals (Abstract; col. 10, lines 15-33). The amount of caffeine is taught to be in the range of 30-150

mg, thus reasonably anticipating the instantly claimed 0.1-100 mg/kg/day and 0.1-10 mg/kg/day (col. 3, lines 59-67). The compositions are administered orally (*i.e.*, as a beverage), thus anticipating the claimed "oral" administration route (col. 4, lines 8-14).

With respect to the claimed "administration" of adenosine and inorganic phosphate, AMP, or ATP, Lehninger is provided as supporting evidence that the consumption of a normal diet will naturally result in the "administration" of ATP and/or AMP as instantly claimed. For example, Lehninger teaches that ATP, ADP, and AMP "...are not trace substances; the sum of their concentrations in the aqueous phase of various types of intact cells is between 2 and 15 mM" (page 289). These nucleotides are present not only in the soluble cytoplasm but also within organelles such as mitochondria and nuclei (id.). Accordingly, it is the Examiner's position that the consumption of a normal diet or a commercial diet plan will naturally result in the consumption of AMP or ATP because these substances are present in all cells, including the cells of beef products, fish products, chicken products, vegetables, etc.

### ***Allowable Subject Matter***

Claims 4-6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES D. ANDERSON whose telephone number is (571)272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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/James D Anderson/

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614